Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL N. ROBERTSON, BRUCE CHESEBRO,
MASAAKI MIYAZAWA, and WILLIAM J. BRITT

Appeal No. 1995-4400
Application 07/694,302

ON BRIEF

Before STONER, Chief Administrative Patent Judge, and WILLIAM F. SMITH and LORIN, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-4, 7-16, 18, and 20, all the claims pending in the application. A copy of the claims is attached to this decision.

The references relied upon by the examiner are:

- Minson 5,045,447 Sept. 3, 1991
- Material Transfer Agreement to Steven Specter, Tampa, Florida, February 28, 1991, for monoclonal antibody 720 [‘91 MTA]
- Material Transfer Agreement to Rex Risser, Madison, Wisconsin, February 20, 1990, for hybridoma cell lines 48 and 720 ['90 MTA]
- Chesebro et al. [Chesebro], "Characterization of Mouse Monoclonal Antibodies Specific for Friend Murine Leukemia Virus-Induced Erythroleukemia Cells: Friend-Specific and FMR-Specific Antigens," Virology, Vol. 112, pp. 131-44 (1981)
- Earl et al. [Earl], "T-Lymphocyte Priming and Protection Against Friend Leukemia by Vaccinia-Retrovirus env Gene Recombinant," Science, Vol. 234, pp. 728-31 (1986)

The rejections[1] are:

1) Claims 1-4, 7, 11, 15, and 16 are rejected under 35 U.S.C. § 102(a) "based on public knowledge or use of the invention in this country before the invention thereof by the applicant for patent" as evidenced by the '91 MTA.

2) Claims 1-4, 7, 11, 15, and 16 are rejected under 35 U.S.C. § 102(b) "based on a public use or sale of the invention" as evidenced by the '90 MTA.

3) Claims 8-10 and 12-14, 18 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over the '90 MTA.[2]

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[1] These are the rejections set forth in the Examiner's Answer of May 20, 1994 (Paper No. 23). A number of other rejections were made in the Final Rejection (Paper No. 14) but do not appear in the Examiner's Answer. We presume those rejections were withdrawn. Also, while claims 1-20 were rejected in the Final Rejection, claims 5, 6, 17, and 19 were excluded from the statements of the rejections in the Examiner's Answer. This is consistent with appellants' Amendment, filed November 22, 1993, accompanying the Brief (Paper Nno. 22), canceling claims 5, 6, 17, and 19. Although the amendment has not been formally entered, the fact that these claims no longer appear in the statements of the rejections in the Examiner's Answer indicates to us that the Examiner intended to enter the amendment. Accordingly, claims 5, 6, 17, and 19 are not under appeal.

[2] The statement of this rejection in the Examiner's Answer includes claim 17 (Paper No. 23, p. 5) rather than claim 18. However, after reviewing the rejection set forth in the Final Rejection, the discussion in appellants' Brief, and the status of the claims (see footnote 1 supra), it is clear that the rejection includes

4) Claims 1-4, 7-16, 18, and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Minson in view of Chesebro and Earl.

DISCUSSION

102(a) over '91 MTA

The facts are:

- On February 28, 1991, Robertson, a co-inventor, signed and dated a Material Transfer Agreement transferring monoclonal antibody 720 to recipient and non-inventor Specter;
- This application (07/694,302) was accorded a filing date of May 2, 1991, designating Robertson, Chesebro, Miyazawa and Britt as co-inventors;
- On May 24, 1991, Britt signed and dated the declaration under 37 CFR § 1.63;
- On May 28, 1991, Miyazawa signed and dated the declaration under 37 CFR § 1.63;
- On May 30, 1991, Robertson signed and dated the declaration under 37 CFR § 1.63; and,
- On June 17, 1991, Chesebro signed and dated the declaration under 37 CFR § 1.63.

The facts include the four declarations under 37 CFR §1.63 but we need not address them. They are relied upon to support appellants' case in rebuttal and extensively discussed. Since the examiner has not satisfied the initial burden of establishing a prima facie case of unpatentability, we do not reach them.

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claim 18 rather than claim 17.

There is no dispute that '91 MTA recites monoclonal antibody 720. The issue is whether a prima facie case of anticipation under 35 U.S.C. § 102(a) has been made out under these facts. We find that it has not.

It is the examiner who bears the initial burden of establishing reasons of unpatentability. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). It is the examiner who must present a prima facie case of anticipation showing that "the invention was known or used by others in this country ... before the invention thereof by the applicant for patent", 35 U.S.C. § 102(a).

After careful review of the examiner's answer (pp. 3-5), we can find only a single paragraph explaining examiner's position (the rest of examiner's discussion is a response to appellants' arguments in the brief). That paragraph states that:

> Claims 1-4, 7, 11, 15, and 16 are rejected under 35 USC §102(a) based upon a public knowledge or use of the invention in this country before the invention thereof by the applicant for a patent. The Material Transfer Agreement to Specter dated February 28, 1991 (hereinafter '"91 MTA"), for monoclonal antibody 720 is evidence that the invention was known or used by others before the filing date of the instant application".

We find the reasoning in this paragraph to be an insufficient foundation for a prima facie case of anticipation of the claims over '91 MTA and for then shifting the burden to appellants to show otherwise.

First of all, "public knowledge or use" is not a condition of unpatentability under 35 USC § 102(a). Examiner is confusing this §102(a) with §102(b).

Secondly, in order for '91 MTA to be anticipatory, it must disclose, expressly or under principles of inherency, each and every element of a claimed invention. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983). Here examiner has rejected not only the claims to monoclonal antibody 720 but also the claims directed to hybridomas. '91 MTA does not mention hybridomas and the examiner does not explain why the single mention of monoclonal antibody 720 in the Agreement expressly or inherently anticipates the claimed hybridomas.

Lastly, examiner does not identify who, Roberston or Specter, satisfies the condition of "others" in determining patentability under 35 U.S.C. § 102(a). We presume it is Robertson since examiner emphasizes that '91 MTA is signed by Robertson alone (examiner's answer, pp. 4-5). In this regard, it is true that '91 MTA is signed only by Roberston and that it does not include the signatures of the other three co-inventors listed on the application file, but we do not see that that alone establishes that "another"[3] person,

[3] "It may not be readily apparent from the statutory language that a printed publication cannot stand as a reference under § 102(a) unless it is describing the work of another. A literal reading might appear to make a prior patent or printed publication "prior art" even though the disclosure is that of the applicant's own work. However, such an interpretation of this section of the statute would negate the one year period afforded under § 102(b) during which an inventor is allowed to perfect, develop and apply for a patent on his invention and publish descriptions of it if he wishes. Illinois Tool v. Solo Cup Co., 461 F.2d 265, 172 USPQ 385 (CA 7), cert. denied, 407 U.S. 916 (1972).

Thus, one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a). Disclosure to the public of one's own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed (or subject matter obvious therefrom) only when the disclosure occurred more than one year prior to the date of the application, that is, when the disclosure creates a one-year time bar, frequently termed a "statutory bar," to the application under §102(b). As stated by this court in In re Facius, 56 CCPA 1348, 1358, 408 F.2d 1396, 1406, 161 USPQ 294, 302 (1969), "But certainly one's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar ." [Emphasis in original.]

Since the publication in this case occurred less than one year before appellant's application, the

i.e., Robertson, and not the four applicants for patent, invented the monoclonal antibody 720 described in the Agreement.

Presumably, had all four inventors signed the Agreement, examiner would not have made the rejection. Clearly, had all the inventors signed the Agreement, there would be no dispute that the monoclonal antibody 720 that was being transferred was "applicants"' own work. Therefore, there would be no question that appellants would have been entitled to transfer their invention to Specter during the one year grace period for filing a patent application accorded inventors under the statute. See 35 U.S.C. § 102(b). Under that circumstance, the '91 MTA would not be evidence of work of "another" and therefore could not have been legally available prior art under 35 U.S.C. §102(a). By emphasizing the difference between the single signer of '91 MTA and the four applicants for patent, examiner appears to be asking us to accord a different status to '91 MTA as legally available prior art under 35 U.S.C. § 102(a) on the grounds that less than all the applicants for patent signed the Agreement. We decline to do so. In our view, this is confusing signing an MTA with inventorship.

All that we are provided is a transfer agreement with a single reference to "Monoclonal Antibody 720" and the fact that it was signed by only one of the four co-applicants. The examiner has not explained why the fact that Robertson signed the transfer

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disclosure comes within the scope of § 102(a) only if the description is not of appellant's own work." In re Katz, 689 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982).

is inconsistent with this application naming four individuals as the inventors of monoclonal antibody 720. The MTA appears to be designed as a business tool - to transfer proprietary material from one entity to another - not as a means for identifying the inventors of the material being transferred. Viewed another way, we know of no reason why any inventor of material to be transferred needs to sign an MTA, as opposed to any person, be they an inventor or non-inventor, who is authorized by the owner of the material to execute such a document.

Accordingly, for these reasons, we find that examiner has not satisfied the initial burden of establishing reasons of unpatentability of the claimed invention. The rejection is reversed.

102(b)/103 over '90 MTA

There are two rejections and they both involve '90 MTA; one is over §102(b) and the other is over §103. We will treat them together.

The facts are:

- On February 20, 1990, Risser, a non-inventor and recipient, signed and dated a Material Transfer Agreement by which Chesebro, a co-inventor and who also signed and dated the agreement (although the date is illegible), agreed "to transfer to [Risser] the following Research Material: hybridoma cell lines 48 and 720" [only the transfer of hybridoma cell line 720 is at issue here - see appellants' Brief p. 7];
- This application (07/694,302) was accorded a filing date of May 2, 1991, designating Robertson, Chesebro, Miyazawa and Britt as co-inventors;
- On September 23, 1992, appellants filed a declaration by Thomas C. Mitchell (Paper No. 13). Therein, Mitchell states that:

- he was "a graduate student in the laboratory of Dr. Rex Risser ... from January, 1987 until September, 1990";
- "Dr. Risser died in September, 1990";
- "In February 1990, Dr. Risser entered an agreement with Dr. Bruce Chesebro ... for the transfer of hybridoma cell lines 48 and 720 to Dr. Risser's laboratory";
- "The transfer of the cell lines was for experiments that I was to perform...";
- "I have knowledge that prior to the transfer..., Dr. Risser and Dr. Chesebro had agreed that the transfer of the cell lines and the use of the antibodies from the cell lines would be confidential and that only use within our laboratory was allowed. The agreement prohibited further transfer of the materials to other persons or other disclosures of the materials without Dr. Chesebro's permission. The use of the materials in Dr. Risser's laboratory was limited to uses described to Dr. Chesebro prior to the transfer";
- "In accordance with the agreement, our uses of the materials was not disclosed by publication of articles or abstracts, presentations at scientific meetings, or otherwise."

The facts include the Mitchell declaration, but we will not address it. The declaration is extensively discussed by the parties as an important fact in determining the issues but we find it unnecessary to address its merits since the examiner has not satisfied the initial burden of establishing a prima facie case of unpatentability.

There is no dispute that '90 MTA is dated more that one year prior to the filing date of the application. The issue is whether '90 MTA evidences a "public use" more that one year prior to the filing date of the application under 35 U.S.C. § 102(b)[4] . Appellants argue

[4] 35 U.S.C. § 102 states, in part, that:
A person shall be entitled to a patent to a patent unless -
...

that '90 MTA "does not indicate public use [appellants' emphasis] of the claimed invention. Thus, the material transfer agreement to Dr. Risser and the transfer itself are not properly deemed prior art and can neither anticipate nor make obvious the claimed subject matter." Brief, p. 7. We agree.

The burden resides with the examiner to establish a prima facie case of anticipation based on the facts in this case. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The burden is on the examiner to establish that '90 MTA demonstrates that the claimed invention - hybridoma cell line 720 - was in public not experimental[5] use. That the examiner has not done.

Examiner merely states (Examiner's Answer, p. 5) that '90 MTA "indicates that the invention was in public use." In our view, that is not enough to satisfy the burden. Examiner has not made the necessary fact-finding to reach that conclusion. In fact, a plain reading of the reference does not support examiner's position. In paragraph 3 of the Agreement, it states that "This Research material will not be used for commercial purposes…." In

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(b) the invention was ... in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, ...

[5] "'The experimental use doctrine operates in the inventor's favor to allow the inventor to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute.' See In re Hamilton, 882 F.2d 1576, 1581, 11 USPQ2d 1890, 1894 (Fed. Cir. 1989) (discussing experimental use in the context of the on-sale bar) (emphasis in original). Providing Cullis, the inventor, with the benefit of Suaudeau's testing is thus contrary to this policy, as Suaudeau was not using or testing the invention for Cullis. Id. Accordingly, we hold that public testing before the critical date by a third party for his own unique purposes of an invention previously reduced to practice and obtained from someone other than the patentee, when such testing is independent of and not controlled by the patentee, is an invalidating public use [our emphasis], not an experimental use."

paragraph 5, it states that "This Research material ... is considered proprietary to Provider." The agreement is replete with statements like these suggestive of control by the inventor of the invention that was transferred to the recipient. Furthermore, to the extent that we understand the contents of the Agreement, '90 MTA appears to require that the material be held in confidence. Based on this and the express language contained in the Agreement, we do not find that the examiner has established that the invention described in '90 MTA was in "public use" more that one year prior to the filing date of the application. Accordingly, we reverse the rejections.

§ 103 over Minson in view of Chesebro and Earl

We reverse this rejection for the reasons stated in Appellants' Brief (pp. 10-13).

The claimed invention is directed to Friend murine leukemia virus (F-MuLV) specific monoclonal antibodies, or binding fragments thereof, specific for an antigenic determinant of a gp85 envelope precursor protein characteristic of a methanol-fixed F-MuLV infected cell.

Minson, the primary reference, describes obtaining monoclonal antibodies reactive to methanol-fixed antigens as set forth in the claims. However, Minson is directed to human papillomavirus (HPV) and not to F-MuLV as required by the claimed invention. While we agree that "Chesebro teaches production of monoclonal antibodies to Friend murine leukemia virus gp70 envelope protein," Examiner's Answer, p. 9, Brief, p. 11; and,

Baxter Int'l, Inc. v. Cobe Labs., Inc., 88 F.3d 1054, 1060-61, 39 USPQ2d 1437, 1442 (Fed. Cir. 1996).

"Earl teaches immunization of mice with recombinant vaccinia virus expressing Friend MuLV gp85", Examiner's Answer, p. 9, Brief, p. 11, nowhere does examiner provide evidence or cogent technical reasoning to equate Minson's HPV with Chesebro's and Earl's F-MuLV. We agree with appellants that the examiner "has failed to demonstrate that HPV and Friend murine leukemia virus (whose epitopes bind antibodies of the present invention) share epitopes or are even closely related." Brief, p. 12. As appellants have pointed out (Brief, p. 12), HPV is a double-stranded DNA virus and Friend MuLV is an RNA retrovirus. Accordingly, we do not see how one of skill would have been led to obtain monoclonal antibodies specific for an antigenic determinant of a gp85 envelope precursor protein characteristic of a methanol-fixed F-MuLV infected cell from this combination of references.

"To establish a prima facie case of obviousness based on a combination of references, there must be a teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant." In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998). While there is no doubt that each of the claimed limitations are taught by the cited references, the mere fact that the prior art could be modified to obtain the claimed process does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Something in the prior art as a whole must suggest the desirability and thus the obviousness of making the combination. Lindemann

Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984). Here the examiner has not pointed to anything in the references which would lead one to the claimed combination and we can find none. The only reason to obtain monoclonal antibodies specific for an antigenic determinant of a gp85 envelope precursor protein characteristic of a methanol-fixed F-MuLV infected cell is provided by appellants' disclosure. It is however impermissible, as examiner has done here, to use appellants' specification as a blueprint to reach the claimed invention from the prior art disclosures. "When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than hindsight gleaned from the invention itself." Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). Accordingly, we hold that the examiner has not established a prima facie case of obviousness of the claims.

REVERSED

BRUCE H. STONER, JR.	)
Chief Administrative Patent Judge	)
	)
	) BOARD OF PATENT
WILLIAM F. SMITH	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
HUBERT C. LORIN	)
Administrative Patent Judge	)

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CLAIMS:

1. A hybridoma which produces a Friend murine leukemia virus (FMuLV) specific monoclonal antibody specific for an antigenic determinant of a gp85 envelope precursor protein characteristic of a methanol-fixed F-MuLV infected cell.

2. The hybridoma according to claim 1, wherein said hybridoma results from the fusion of a myeloma cell and a spleen cell.

3. The hybridoma according to claim 2 wherein said myeloma cell is derived from a mouse.

4. The hybridoma according to claim 3 wherein said myeloma cell is X63-Ag8.653.

7. A hybridoma producing monoclonal antibody 720, IgG1.

8. A hybridoma producing monoclonal antibody 721, IgG2a.

9. A hybridoma producing monoclonal antibody 722, IgG2a.

10. A hybridoma producing monoclonal antibody 723, IgG3.

11. A monoclonal antibody having the binding characteristics of the monoclonal antibody produced by the hybridoma according to claim 7, or binding fragment thereof.

12. A monoclonal antibody having the binding characteristics of the monoclonal antibody produced by the hybridoma according to claim 8, or binding fragment thereof.

13. A monoclonal antibody having the binding characteristics of the monoclonal antibody produced by the hybridoma according to claim 9, or binding fragment thereof.

14. A monoclonal antibody having the binding characteristics of the monoclonal antibody produced by the hybridoma according to claim 10, or binding fragment thereof.

15. A Friend murine leukemia virus (FMuLV) specific monoclonal antibody, or binding fragment thereof, specific for an antigenic determinant of a gp85 envelope precursor protein characteristic of a methanol-fixed F-MuLV infected cell.

16. The monoclonal antibody according to claim 15 wherein said antibody is of the IgG class.

18. A diagnostic kit comprising a conjugate comprising:
i) at least one monoclonal antibody according to claim 15, and
ii) a label.

20. A diagnostic kit comprising a conjugate comprising:
i) at least one monoclonal antibody according to claims 11, 12, 13, 14 and
ii) a label.